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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,675	07/16/2004	Yuji Imai	IMAI13	5140
1444 7590 10/10/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER WALICKA, MALGORZATA A	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 10/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,675

Applicant(s)

IMAI ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-17,22-24 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-17,22-24 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The Amendment filed August 7, 2007 is acknowledged. Claims 1-14, 18, 25 and 29 have been currently cancelled; claims 19-21 were previously cancelled. Claims 15, 16, 27, 28 and 29 have been amended. Claims 15-17, 22-24, and 27-29 are pending and under examination.

DETAILED ACTION

Objections and rejections not repeated below are moot because claims 1-13 have been cancelled and other claim have been amended.

Rejections

35 USC 112 second paragraph

Claim 22-24 and 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 23 are lacking an antecedent for inflammatory dermal disease in the base claim 15.

Claim 22 is also rejected for recitation of "chronic intractable dermal disease" which is absent form the base claim 15. Furthermore the term "chronic intractable dermal disease" is not taught by the claims or specification. Many dermal diseases can be considered intractable. The indefinite recitation renders the claim indefinite.

Claim 22 also seems not to further limit claim 15, because the genus of chronic intractable dermal disease is larger than the genus of psoriasis species.

Claims 23 does not further limit claim 15 because claim 15 already recites psoriasis.

Claim 24 is confusing in recitation "a compound which has not been known as an inhibitor for **the** phospholipase A₂ [emphasis added]". The tested compound is to be an inhibitor of any phospholipase A₂ thus the phrase should be "a compound which has not been known as an inhibitor for **a** phospholipase A₂". If the test compound is an inhibitor of the phospholipase of claim 15, then there is no point to test it.

Claim 28 is indefinite because the claim does not explicitly state the stringent hybridization conditions that are to be used in the claimed method. One skilled in the art realizes that there are many sets of hybridization conditions in the art that are used for identifying DNA molecules by hybridization. It is noted that Applicants themselves used conditions presented on page 48 lines 6-11.

Scope of enablement

Claims 15-17, 22-24 and 27-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the human phospholipase A2 of SEQ ID NO: 9, its encoding DNA of SEQ ID NO: 8 and methods of their use, does not reasonably provide enablement for a polypeptide encoded by a nucleic acid molecule capable of hybridizing with a complement of a nucleic having the nucleotide sequence of SEQ ID NO: 8 at 50 to 60° C for 16 hours in 6xSSC or in a hybridization solution having a salt concentration equivalent thereto, prewash in 6xSSC and washing in 1xSSC, wherein the prewashing and washing may be alternatively performed in a hybridization solution having a salt concentration equivalent to 6xSSC.

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The language of the claim does not state the temperature of washing, thus it is understood that the temperature of washing is an ambient temperature.

The hybridization conditions recited by the claims are of medium stringency, thus nature and breath of the claimed invention encompasses polynucleotides that are less than 90% identical to SEQ ID NO: 8 and originate from any natural or man-made source.

While methods of selection of DNA molecules by hybridization under particular condition is within the skills of the skilled artisan, selection under conditions recited by the claims does not assure that the selected DNA molecule will be encoding a polypeptide having that same phospholipase A2 activity as that of SEQ ID NO: 9 encoded by DNA of SEQ ID NO: 8. The selected DNA molecules must be tested for encoding the enzymatic activity that is to be the same as that of SEQ ID NO: 9, which is out of routine experimentation. When the isolated DNA molecule is for example 90% identical to SEQ ID NO: 8, then 0.10 x 3587 nt, are changed, which creates an astronomical number of DNA molecules which can be calculated from the formula $[3587! \times 3^{359}] / [(3587-359)! \times 359!]$. All these molecules have to be expressed and their enzymatic activity tested. This forces one skilled in the art to extensive experimentation which is not routine, wherein the probability of success in obtaining the claimed invention is low.

Examiner concludes that without limiting the hybridization conditions to those quoted in the sentence bridging page 16 and 17, experimentation left to those in the art is improperly extensive and undue.

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Conclusion

Claims 15 –1, 22-24 and 27-29 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status

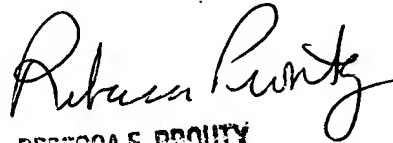
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information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.

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Patent Examiner


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